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File: USPT

May 14, 1996

US-PAT-NO: 5516530

DOCUMENT-IDENTIFIER: US 5516530 A

TITLE: Porous shaped delivery devices and method of producing thereof

DATE-ISSUED: May 14, 1996

## INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
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Puz; Michael J.	Pawcatuck	CT		

US-CL-CURRENT: 424/473; 424/487

## CLAIMS:

We claim:

1. A porous, compressed shaped delivery device comprising:

a) about 5% to about 95% water soluble polymer; and

b) about 0.01 mg to about 1000 mg active agent; wherein said device has a porosity of at least about 85%, said porosity void of active agent and said device has a predetermined molded shape over the entire device surface.

2. The device as recited in claim 1 wherein said water soluble polymer is gelatin, pectin, hydroxypropyl cellulose, poly(N-vinylpyrrolidone) or carhomer.

3. The device as recited in claim 2 wherein said beneficial agent is a pharmaceutical agent.

4. The device as recited in claim 3 wherein said pharmaceutical agent is fluconazole, piroxicam or pseudoephedrine HCl, azithromycin, sertraline, or cetirizine.

5. The device as recited in claim 4 wherein said device comprises about 5% to about 30% water soluble polymer.

6. A method for making a porous shaped delivery device comprising:

a). disposing a formulation into a first die, said formulation comprising about 0.01 mg to about 1000 mg beneficial agent and about 1% to about 10% water soluble polymer;

b). freezing said formulation to form a frozen predevice;

c). contacting a second die with the exposed frozen predevice surface at a pressure, temperature and time sufficient to locally liquify, shape and refreeze said surface; and

d). lyophilizing said frozen predevice to form said porous, shaped delivery device, said device having aporosity of about 85% to about 98%, said porosity void of active agent.

7. The method as recited in claim 6 wherein said formulation includes a water soluble polymer.

8. The method as recited in claim 7 wherein said formulation includes a pharmaceutical agent.

9. The method as recited in claim 8 wherein said formulation includes at least about 85% water.

10. The method as recited in claim 9 wherein said pressure and temperature ranges from 0.5 kg/cm.<sup>sup.2</sup> at 200.degree. C. to 9,000 kg/cm.<sup>sup.2</sup> at -78.degree. C. over a period of 1 second to 1 minute.

11. The method as recited in claim 9 wherein said water soluble polymer is gelatin, pectin, hydroxypropyl cellulose, poly(N-vinylpyrrolidone), or carbomer.

12. The method as recited in claim 11 wherein said pharmaceutical agent is fluconazole, piroxicam, pseudoephedrine HCl, azithromycin, sertraline, or cetirizine.

13. The method as recited in claim 12 wherein said pressure and temperature ranges from 2,500 kg/cm.<sup>2</sup> at -30.degree. C. to 450 kg/cm.<sup>2</sup> at 60.degree. C. over 1 second to 10 seconds.

14. The method as recited in claim 13 wherein said pharmaceutical agent is fluconazole and said water soluble polymers are gelatin and carhomer.

15. The method as recited in claim 14 wherein said device contacts a mold release material integral to or applied to said dies.

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## ASSIGNEE-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY	TYPE CODE
Pfizer Inc.	New York	NY			02

APPL-NO: 08/ 244700 [PALM]

DATE FILED: June 1, 1994

## PARENT-CASE:

This application was filed under 35 U.S.C. .sectn.371 based on PCT/US92/09273, which was filed on Nov. 4, 1992, which was a continuation-in-part of U.S. application Ser. No. 07/811,411 which was filed on Dec. 20, 1991 and is now abandoned.

## PCT-DATA:

APPL-NO	DATE-FILED	PUB-NO	PUB-DATE	371-DATE	102(E)-DATE
PCT/US92/09273	November 4, 1992	WO93/12770	Jul 8, 1993	Jun 1, 1994	Jun 1, 1994

INT-CL: [06] A61 K 9/44

US-CL-ISSUED: 424/473; 424/487

US-CL-CURRENT: 424/473; 424/487

FIELD-OF-SEARCH: 424/78.08, 424/487, 424/473

PRIOR-ART-DISCLOSED:

U.S. PATENT DOCUMENTS

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	PAT-NO	ISSUE-DATE	PATENTEE-NAME	US-CL
<input type="checkbox"/>	<u>3885026</u>	May 1975	Heinemann et al.	424/14
<input type="checkbox"/>	<u>4134943</u>	January 1979	Kaitsch et al.	264/28
<input type="checkbox"/>	<u>4217898</u>	August 1980	Theeuwes	424/473
<input type="checkbox"/>	<u>4305502</u>	December 1981	Gregory et al.	206/532

## FOREIGN PATENT DOCUMENTS

FOREIGN-PAT-NO	PUBN-DATE	COUNTRY	US-CL
0081912	November 1982	EP	
0084705	November 1982	EP	
9109591	July 1991	WO	

ART-UNIT: 152

PRIMARY-EXAMINER: Webman; Edward J.

## ABSTRACT:

High strength, high porosity delivery devices have a shaped surface and disintegrate quickly in an aqueous medium. The devices can be prepared by disposing a formulation in a die to form a frozen predevice. A second die is contacted with the frozen formulation surface at a pressure and temperature for a time sufficient to locally momentarily liquify and shape the device surface. The shaping is followed by lyophilization.

15 Claims, 7 Drawing figures